

510(k) Summary

Sponsor Stryker Orthopaedics
325 Corporate Drive
Mahwah, NJ 07430

Contact Person Shikha Khandelwal
Regulatory Affairs Specialist
Howmedica Osteonics Corp
Shikha.Khandelwal@stryker.com
Ph: 201-831-6921 Fax: 201-831-3921 **NOV 26 2013**

Date Prepared: August 20, 2013

Proprietary Name: Triathlon® Titanium® Metal-Backed Patella

Common Name: Total Knee Joint Replacement

Classification Name: Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis. (888.3565)
Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis (888.3560)

Product Codes: MBH, JWH

Legally Marketed Devices to Which Substantial Equivalence is Claimed:

- Triathlon® Titanium® Tibial Baseplate (K123486)
- Triathlon® Metal-Backed Patella (K061521)
- Triathlon® X3 Patellar Components (cleared as part of the Triathlon® X3™ UHMWPE Tibial Inserts and Patellar Components, K051146)
- Triathlon® Asymmetric and Symmetric Patellar Components (cleared as part of the Triathlon® CR Total Knee System, K040267)
- Scorpio® X3 Recessed Patella (cleared as part of the Scorpio® X3™ UHMWPE Tibial Inserts and Scorpio® X3™ UHMWPE Patellar Components, K051977)

Device Description: The Triathlon® Titanium® Metal-Backed Patella is an extension of the Triathlon® Total Knee System product line for use in primary and revision Total Knee Arthroplasty. It is a sterile, single-use, non-modular metal-backed patella that is manufactured from UHMWPE (ASTM F648) and commercially pure titanium (ASTM F1580). The device is offered in symmetric and asymmetric designs that are available in multiple sizes. The metal-backing features a porous-coated posterior surface and three porous-coated pegs to provide cemented or cementless fixation to bone.

Intended Use: The Triathlon® Titanium® Metal-Backed Patella is intended for cemented or cementless applications when resurfacing the surgically prepared patella as part of primary or revision Total Knee Arthroplasty (TKR). The Triathlon® Titanium® Metal-Backed Patella is compatible for use with components of the cemented Triathlon® PS Total Knee System (K031729, K042993), the cemented Triathlon® CR Total Knee System (K040267, K042883), the Triathlon® TS Total Knee System (K070095, K072221), the cementless Triathlon® CR and PS Total Knee Systems with and without HA (K051380), the Triathlon® Universal Knee System components (K053514), the Triathlon® Low Profile Tibial Baseplate (K062037), the Triathlon® Screw Fixation Tibial Baseplate (K072575), the Triathlon® Titanium® Tibial Baseplate (K123486), the Triathlon® All-Polyethylene Tibia (K123166), the Triathlon® X3™ Tibial Inserts (K051146) and the Triathlon® CS Lipped Tibial Inserts (K063423).

Indications:

General Total Knee Arthroplasty (TKR) Indications:

- Painful, disabling joint disease of the knee resulting from: noninflammatory degenerative joint disease (including osteoarthritis, traumatic arthritis, or avascular necrosis), rheumatoid arthritis or post-traumatic arthritis.
- Post-traumatic loss of knee joint configuration and function.
- Moderate varus, valgus, or flexion deformity in which the ligamentous structures can be returned to adequate function and stability.
- Revision of previous unsuccessful knee replacement or other procedure.
- Fracture of the distal femur and/or proximal tibia that cannot be stabilized by standard fracture -management techniques.

The Triathlon® Titanium® Tibial Baseplate and Titanium® Metal-Backed Patella components are indicated for both uncemented and cemented use.

The Triathlon® Total Knee System beaded and beaded with Peri-Apatite components are intended for uncemented use only.

The Triathlon® All Polyethylene tibial components are indicated for cemented use only.

Additional Indications for Posterior Stabilized (PS) and Total Stabilizer (TS) Components:

- Ligamentous instability requiring implant bearing surface geometries with increased constraint.
- Absent or non-functioning posterior cruciate ligament.
- Severe anteroposterior instability of the knee joint.

Additional Indications for Total Stabilizer (TS) Components:

- Severe instability of the knee secondary to compromised collateral ligament integrity or function.

Indications for Bone Augments:

- Painful, disabling joint disease of the knee secondary to: degenerative arthritis, rheumatoid arthritis, or post-traumatic arthritis, complicated by the presence of bone loss.
- Salvage of previous unsuccessful total knee replacement or other surgical procedure, accompanied by bone loss.

Summary of Technological Characteristics: Device comparisons and performance testing show that the Triathlon® Titanium® Metal-Backed Patella is substantially equivalent to its predicates in terms of intended use, indications, design, materials, performance characteristics and operational principles.

Non-Clinical Testing: The following non-clinical laboratory testing was performed to determine substantial equivalence:

- Elemental Composition of the Bone-apposing Materials (ASTM E1941, ASTM E1447, ASTM E1409)
- Metallurgical and Morphological Properties of the Bone-apposing Materials (ASTM E112, ASTM F1854)
- Mechanical Properties of the Bone-apposing Materials (ASTM F1147, ASTM F1044, ASTM F1160, ASTM E8)
- Plastic Deformation of the Porosity (ASTM F1854)
- Static Tensile Bond Strength of the UHMWPE/Metal Interface
- Static Peg Shear Strength
- Patello-Femoral Contact Stress/Contact Area
- Malaligned Endurance Testing
- Patellar Subluxation Testing

Clinical Testing: Clinical testing was not required as a basis for substantial equivalence.

Conclusion: The Triathlon® Titanium® Metal-Backed Patella is substantially equivalent to the predicate devices identified in this premarket notification.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

November 26, 2013

Stryker Orthopaedics
Ms. Shikha Khandelwal
Regulatory Affairs Specialist
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K132624

Trade/Device Name: Triathlon[®] Titanium[®] Metal-Backed Patella

Regulation Number: 21 CFR 888.3565

Regulation Name: Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis

Regulatory Class: Class II

Product Code: MBH, JWH

Dated: August 29, 2013

Received: August 30, 2013

Dear Ms. Khandelwal:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

Page 2 –Ms. Shikha Khandelwal

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Lori A. Wiggins

for
Mark Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K132624

Device Name: Triathlon® Tritanium® Metal-Backed Patella

Indications for Use:

General Total Knee Arthroplasty (TKR) Indications:

- Painful, disabling joint disease of the knee resulting from: noninflammatory degenerative joint disease (including osteoarthritis, traumatic arthritis, or avascular necrosis), rheumatoid arthritis or post-traumatic arthritis.
- Post-traumatic loss of knee joint configuration and function.
- Moderate varus, valgus, or flexion deformity in which the ligamentous structures can be returned to adequate function and stability.
- Revision of previous unsuccessful knee replacement or other procedure.
- Fracture of the distal femur and/or proximal tibia that cannot be stabilized by standard fracture -management techniques.

The Triathlon® Tritanium® Tibial Baseplate and Tritium® Metal-Backed Patella components are indicated for both uncemented and cemented use.

The Triathlon® Total Knee System beaded and beaded with Peri-Apatite components are intended for uncemented use only.

The Triathlon® All Polyethylene tibial components are indicated for cemented use only.

Additional Indications for Posterior Stabilized (PS) and Total Stabilizer (TS) Components:

- Ligamentous instability requiring implant bearing surface geometries with increased constraint.
- Absent or non-functioning posterior cruciate ligament.
- Severe anteroposterior instability of the knee joint.

Additional Indications for Total Stabilizer (TS) Components:

- Severe instability of the knee secondary to compromised collateral ligament integrity or function.

Indications for Bone Augments:

- Painful, disabling joint disease of the knee secondary to: degenerative arthritis, rheumatoid arthritis, or post-traumatic arthritis, complicated by the presence of bone loss.
- Salvage of previous unsuccessful total knee replacement or other surgical procedure, accompanied by bone loss.

Prescription Use
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

